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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANDRES, JANET L	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,924	CENTER ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30,31,33 and 34* is/are allowed.

6)☐ Claim(s) *29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 28 July 2003 is acknowledged. Claims 21 and 29-34 are pending in this application. To expedite prosecution of the application, peptides restricted in the office action of paper no. 5 are rejoined although separate searches were required. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to claim 30 as containing sequences not referred to by a sequence identifier is withdrawn in response to Applicant's amendment to this claim.

3. The rejection of claims 21 and 35 under 35 U.S.C. 102(b) as anticipated by the '838 patent, Moreland et al., Panayi et al., Choy et al., Connolly et al., Wending et al., and Reece et al. is withdrawn in response to Applicant's amendment.

5. The rejection of claim 21 under 35 U.S.C. 112, first paragraph, as lacking enablement for pharmaceutical compositions is withdrawn in response to Applicant's indication of the supportive teachings of Yoshimoto et al. and Keats et al.

Objections Maintained/New Grounds of Rejection

3. The objection to the specification is maintained because the description of figure 7 has not been corrected and the reference to the color blue on p. 53 has not been addressed.

4. Claims 21 and 29 are newly rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. This claim is drawn to an antibody against a peptide consisting of four amino acids. The art, however, teaches that a minimum of six amino acids is required for antigenicity. See Harlow et al., Antibodies, 1988, p. 76. Since antibodies are contemplated but not actually

provided by the instant specification, and the art teaches that the antigen is too small, one of skill in the art could not predictably make the antibodies as claimed.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 5846933 (Korngold et al., 1998) in view of Harlow et al.

The '933 patent teaches SEQ ID NOs 6 and 51, both of which consist of LSDSGQVL, which are residues 7-14 of instant SEQ ID NO: 12 (column 5, line 5, and column 18, lines 64-65) and teaches that these peptides have therapeutic utility. As stated above, 6 amino acids is considered in the art to be sufficient to function as an epitope; thus, antibodies against the sequence taught by the '933 patent would inherently interact with instant SEQ ID NO: 12. The '933 patent fails to teach such antibodies. Harlow et al. teaches many procedures and uses for antibodies, including such functions as quantitation by immunoassay (p. 555). It would have been obvious to one of ordinary skill in the art to combine the teachings of the '933 patent with

those of Harlow et al. to produce antibodies to this sequence, which would also be antibodies to Applicant's SEQ ID NO: 12. One of ordinary skill would have been motivated to do so because the '930 patent teaches that this is a useful peptide, and Harlow et al. teaches, many uses for antibodies, including quantitiaton. Thus one of ordinary skill would expect to find many uses for such antibodies, including the ability to measure levels of a therapeutically useful peptide.

CLAIMS 21, 29 AND 32 ARE REJECTED. CLAIMS 30, 31, 33, AND 34 ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[yvonne.eyler@uspto.gov]**.

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 20, 2003

JANET ANDRES
PATENT EXAMINER